

001 0 8 1999

Attorney's Docket No. A32362 072396.0174

Baker & Botts, L.L.P.

Applicant or Patentee: Giannoukakis et al.

Serial No.: 09/320,767 Filed: May 27, 1999

For: GENE TRANSFER TO PANCREATIC β CELLS FOR PREVENTION OF ISLET DYSFUNCTION

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27(d)) - NONPROFIT ORGANIZATION**

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF ORGANIZATION University of Pittsburgh of the Commonwealth System of Higher Education

ADDRESS OF ORGANIZATION 911 William Pitt Union, Pittsburgh, PA 15260

TYPE OF ORGANIZATION University

☒ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION

☐ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE]26 USC 501(a) and 501(c)(3))

☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA

(NAME OF STATE)

(CITATION OF STATUTE)

☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) and 501(c)(3)) IF LOCATED IN THE UNITED STATES OF AMERICA

☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA

(NAME OF STATE)

(CITATION OF STATUTE)

I hereby declare that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code with regard to the invention entitled GENE TRANSFER TO PANCREATIC β CELLS FOR PREVENTION OF ISLET DYSFUNCTION

by inventor(s) NICK GIANNOUKAKIS, PAUL D. ROBBINS, AND MASSIMO TRUCCO
described in

☐ the specification filed herewith

☒ Application Serial No. 09/320,767, filed May 27, 1999.

☐ Patent No. , issued .

I hereby declare that the rights under contract or law have been conveyed to and remain with the nonprofit organization with regard to the above identified invention.

If the rights held by the nonprofit organization are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who

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could not qualify as a small business concern under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e). *Note: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME _____

ADDRESS _____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

NAME _____

ADDRESS _____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Frances J. ConnellTITLE IN ORGANIZATION Director, Office of Technology ManagementADDRESS OF PERSON SIGNING University of Pittsburgh, 200 Gardner Steel Conference Center
Pittsburgh, PA 15260SIGNATURE *Frances J. Connell*DATE *July 13, 1999*

DCI U S 1999

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Giannoukakis et al.

Serial No.: 09/320,767

Examiner: TBA

Filed: May 27, 1999

Group Art Unit: 1643

For: GENE TRANSFER TO PANCREATIC β CELLS FOR PREVENTION OF ISLET DYSFUNCTION

SUBMISSION OF VERIFIED STATEMENTS CLAIMING SMALL ENTITY STATUS

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Assistant Commissioner for Patents, Washington, D.C. 20231

October 5, 1999

Date of Deposit

Carmella L. Stephens

Attorney Name

41,328

PTO Registration No.

Carmella L. Stephens

Signature

October 5, 1999

Date of Signature

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants submit herewith Verified Statement Claiming Small Entity Status relating to the above-identified patent application by Assignee University of Pittsburgh of the Commonwealth System of Higher Education. A copy of the Assignment documents, submitted for Recordation on even date herewith, is attached. Accordingly, it is requested that small entity status be granted to this application.

Respectfully submitted,

Carmella L. Stephens

Rochelle K. Seide
Patent Office Reg. No. 32,300
Attorney for Applicant(s)

Carmella L. Stephens
Patent Office Reg. No. 41,328
Agent for Applicant(s)

(212) 408-2500

**COMBINED DECLARATION
AND POWER OF ATTORNEY****(Original, Design, National Stage of PCT, Divisional, Continuation or C-I-P Application)**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

GENE TRANSFER TO PANCREATIC β CELLS FOR PREVENTION OF ISLET DYSFUNCTION

This declaration is of the following type:

- ☒ original
- ☐ design
- ☐ national stage of PCT.
- ☐ divisional
- ☐ continuation
- ☐ continuation-in-part (C-I-P)



the specification of which: *(complete (a), (b), or (c))*

- (a) ☐ is attached hereto.
- (b) ☒ was filed on May 27, 1999 as Application Serial No. 09/320,767.
- (c) ☐ was described and claimed in PCT International Application No. filed on and was amended on *(if applicable)*.

Acknowledgement of Review of Papers and Duty of Candor

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of the subject matter claimed in this application in accordance with Title 37, Code of Federal Regulations § 1.56.

☐ In compliance with this duty there is attached an information disclosure statement. 37 CFR 1.98.

Priority Claim

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT International Application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT International Application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application on which priority is claimed

(complete (d) or (e))

- (d) ☒ no such applications have been filed.
- (e) ☐ such applications have been filed as follows:

PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO SAID APPLICATION			
COUNTRY	APPLICATION NO.	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)
			PRIORITY CLAIMED UNDER 35 USC 119 <input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
ALL FOREIGN APPLICATION(S), IF ANY, FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO SAID APPLICATION			
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

Claim for Benefit of Prior U.S. Provisional Application(s)

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

Provisional Application Number	Filing Date

Claim for Benefit of Earlier U.S./PCT Application(s) under 35 U.S.C. 120

(complete this part only if this is a divisional, continuation or C-I-P application)

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior application(s) in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose information as defined in Title 37, Code of Federal Regulations, § 1.56 which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
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(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
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Power of Attorney

As a named inventor, I hereby appoint Dana M. Raymond, Reg. No. 18,540; Frederick C. Carver, Reg. No. 17,021; Francis J. Hone, Reg. No. 18,662; Joseph D. Garon, Reg. No. 20,420; Arthur S. Tenser, Reg. No. 18,839; Ronald B. Hildreth, Reg. No. 19,498; Thomas R. Nesbitt, Jr., Reg. No. 22,075; Robert Neuner, Reg. No. 24,316; Richard G. Berkley, Reg. No. 25,465; Richard S. Clark, Reg. No. 26,154; Bradley B. Geist, Reg. No. 27,551; James J. Maune, Reg. No. 26,946; John D. Murnane, Reg. No. 29,836; Henry Tang, Reg. No. 29,705; Robert C. Scheinfeld, Reg. No. 31,300; John A. Fogarty, Jr., Reg. No. 22,348; Louis S. Sorell, Reg. No. 32,439; Rochelle K. Seide Reg. No. 32,300; Gary M. Butter, Reg. No. 33,841; Marta E. Delsignore, Reg. No. 32,689; and Lisa B. Kole, Reg. No. 35,225 of the firm of BAKER & BOTTS, L.L.P., with offices at 30 Rockefeller Plaza, New York, New York 10112, as attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith

SEND CORRESPONDENCE TO: BAKER & BOTTS, L.L.P. 30 ROCKEFELLER PLAZA, NEW YORK, N.Y. 10112 CUSTOMER NUMBER: 21003	DIRECT TELEPHONE CALLS TO: BAKER & BOTTS, L.L.P. (212) 705-5000
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge

that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

FULL NAME OF SOLE OR FIRST INVENTOR	LAST NAME Giannoukakis	FIRST NAME Nick	MIDDLE NAME	
RESIDENCE & CITIZENSHIP	CITY Pittsburgh	STATE or FOREIGN COUNTRY Pennsylvania	COUNTRY OF CITIZENSHIP Canada	
POST OFFICE ADDRESS	POST OFFICE ADDRESS 230 N. Craig Street, Apt. 707	CITY Pittsburgh	STATE or COUNTRY Pennsylvania	ZIP CODE 15213
DATE 9/23/99	SIGNATURE OF INVENTOR <i>Nick Giannoukakis</i>			
FULL NAME OF SECOND JOINT INVENTOR, IF ANY	LAST NAME Robbins	FIRST NAME Paul	MIDDLE NAME D.	
RESIDENCE & CITIZENSHIP	CITY Mt. Lebanon	STATE or FOREIGN COUNTRY Pennsylvania	COUNTRY OF CITIZENSHIP United States	
POST OFFICE ADDRESS	POST OFFICE ADDRESS 191 Main Entrance Drive	CITY My. Lebanon	STATE or COUNTRY Pennsylvania	ZIP CODE 15228
DATE 9/23/99	SIGNATURE OF INVENTOR <i>Paul Robbins</i>			
FULL NAME OF THIRD JOINT INVENTOR, IF ANY	LAST NAME Trucco	FIRST NAME Massimo	MIDDLE NAME	
RESIDENCE & CITIZENSHIP	CITY Pittsburgh	STATE or FOREIGN COUNTRY Pennsylvania	COUNTRY OF CITIZENSHIP United States/Italy	
POST OFFICE ADDRESS	POST OFFICE ADDRESS 4309 Parkman Avenue	CITY Pittsburgh	STATE or COUNTRY Pennsylvania	ZIP CODE 15213
DATE 9/23/99	SIGNATURE OF INVENTOR <i>Massimo Trucco</i>			
FULL NAME OF FOURTH JOINT INVENTOR, IF ANY	LAST NAME	FIRST NAME	MIDDLE NAME	
RESIDENCE & CITIZENSHIP	CITY	STATE or FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP	
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE or COUNTRY	ZIP CODE
DATE	SIGNATURE OF INVENTOR			
FULL NAME OF FIFTH JOINT INVENTOR, IF ANY	LAST NAME	FIRST NAME	MIDDLE NAME	
RESIDENCE & CITIZENSHIP	CITY	STATE or FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP	
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE or COUNTRY	ZIP CODE
DATE	SIGNATURE OF INVENTOR			
FULL NAME OF SIXTH JOINT INVENTOR, IF ANY	LAST NAME	FIRST NAME	MIDDLE NAME	
RESIDENCE & CITIZENSHIP	CITY	STATE or FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP	
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE or COUNTRY	ZIP CODE
DATE	SIGNATURE OF INVENTOR			

FULL NAME OF SEVENTH JOINT INVENTOR, IF ANY	LAST NAME	FIRST NAME	MIDDLE NAME	
RESIDENCE & CITIZENSHIP	CITY	STATE or FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP	
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE or COUNTRY	ZIP CODE
DATE	SIGNATURE OF INVENTOR			

Check proper box(es) for any added page(s) forming a part of this declaration

- ☐ Signature for ninth and subsequent joint inventors. Number of pages added _____.
- ☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor.
Number of pages added _____.
- ☐ Signature for inventor who refuses to sign, or cannot be reached, by person authorized under 37 CFR 1.47.
Number of pages added _____.